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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,346	06/28/2001	Wayne D. Comper	48643-015	2638

7590 11/05/2003

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EXAMINER	
CHEN, STACY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/05/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/893,346	COMPER, WAYNE D.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14,16-18 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-14,16-18 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment received August 18, 2003 is acknowledged and entered. Claims 1-5, 7-14, 16-18 and 20-24 are pending and examined.

2. The objection to claims 21 and 24 is withdrawn in view of Applicant's amendment. The rejection of claims 8, 10, 18, 20 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of Applicant's arguments.

3. For clarification purposes, intact modified protein is a protein that elutes at less than, equal to or greater than the native protein. Since the method steps refer to detecting the intact modified protein, it was not readily apparent how one would detect intact modified protein since both the intact modified and the native protein can elute at the same location in a separation medium, such as HPLC. However, the specification clearly teaches (page 18, paragraph 97) that while the intact modified protein and the native protein can elute at the same location in a separation medium, the step of detecting intact modified protein also involves an analysis for ligand binding which ultimately results in the determination of an amino acid sequence. The determination of an amino acid sequence indicates the differences between the intact modified protein and the native protein. Applicant's claims also include antibody detection of the intact modified protein. The ability to detect intact modified proteins via antibodies was questioned in the previous enablement rejections because the specification teaches that intact modified protein cannot be detected by conventional radioimmunoassays using available antibodies (page 10, paragraph 50). However, for the same reasons above, once the intact modified protein is detected by separation and analysis of amino acid sequence, antibodies can be made by known methods in the art that are specific for the intact modified proteins.

Comper Declaration

4. The declaration of Dr. Wayne Comper filed August 18, 2003, under 37 CFR 1.132 is acknowledged and has been considered. The declaration outlines an experiment performed under the supervision of Dr. Comper detecting radiolabelled transferrin and another experiment detecting radiolabelled IgG in rats. The two groups of rats are identified as untreated controls, and rats with experimental diabetes induced by administration of STZ. The results from the experiments are not clear in terms of their leading to the conclusion that detection of immunoreactive and immuno-unreactive protein in a sample provides an accurate protein profile of the sample, which can be used to accurately diagnose renal complications of disease before the onset of kidney degeneration.

The claims recite a method in which native and intact modified protein are detected in the urine. Applicant's experiment in the declaration estimates intact protein in plasma, and estimates ghost protein in urine. Estimates of intact protein and ghost protein do not lead to an accurate protein profile of the sample. Further, the claims are drawn to a method in which protein is collected and detected over time. The experiment outlined in the declaration appears to be a one-time event.

In both sets of rats, ghost transferrin was detected. Since the diabetic rats showed a higher level of ghost transferrin, Applicant concluded that the diabetic rats are predisposed to kidney degeneration. However, the method claims require that the measurements be taken over time. Further, the amount of ghost transferrin is merely estimated. This estimation does not provide an accurate protein profile of the sample. In the experiment detecting IgG, Applicant

concludes that since the amount of ghost transferrin in the control rats and diabetic rats was the same, that ghost IgG appears later than transferrin. However, this was not shown because only one sample of plasma and urine was analyzed instead of more than one sample over a period of time.

The results from the experiment outlined in the Comper declaration do not lead one to conclude accurate diagnosis of renal complications of disease prior to the onset of kidney degeneration can be detected by measuring immunoreactive and immuno-unreactive protein commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

5. Claims 1-5, 7, 13, 14, 16, 17, 20, 21 and 23 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for reasons of record and in view of the Comper Declaration discussed above. The claims are drawn to a method that assesses therapeutic effectiveness of a treatment agent, requiring the detection of an increase in intact modified protein. While the prior art shows that proteins in various forms are excreted through urine in patients having renal disease, the ability to detect intact modified protein (ghost protein) of any protein and relating it to renal disease is not enabled commensurate in scope with the claims. The Comper Declaration shows an experiment detecting intact and ghost transferrin and IgG. The method steps in the experiment are not used in the method claimed. Further, the fact that it was not determined when the ghost IgG of the diabetic rats would be higher than the intact IgG, shows that it would require undue experimentation to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

6. Claims 1, 20 and dependent claims remain rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The methods involve detection of both native and intact modified protein, however, the presence of native or intact modified protein is used to correlate effectiveness of the treatment agent. It is unclear why both forms are detected, yet only one is used in the correlation step.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

No claim is allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

James C. Housel

JAMES HOUSEL 11/3/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Stacy B. Chen
November 3, 2003